

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 51-R-0079

CUSTOMER NUMBER: 21555

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Gene Logic Laboratories Inc
610 Professional Drive
Gaithersburg, MD 20879

Telephone: (301)-216-3889

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	96	258	51	3	312
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	933	2032	13	2978
7. Hamsters	0	0	0	0	0
8. Rabbits	24	1482	119	1	1602
9. Non-human Primates	100	99	110	1	210
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

b6,b7c

DATE SIGNED

11-28-05

ANNUAL REPORT OF RESEARCH FACILITY

Certificate Number: 51-R-0079

Customer Number: 21555

NOV 30 2005

3. Reporting Facility

Gene Logic Laboratories Inc.
(Formerly Therimmune Research Corporation)

b2, b7f

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY

Column E Explanation (Amendment to 2005 Report)

I. DOGS

Species: Beagle Dog

Study: 04136

Animal Number: b4

Test Group/Sex: 3F

Justification:

Current Food and Drug Administration (FDA) policy requires the use of rodent and non-rodent species for chemical compounds when data will be submitted for Individual New Drug application. Study designs follow the Good Laboratory Practice (GLP) for Non-clinical Laboratory Studies (FDA 21 CFR Part 58) and are based on International Committee on Harmonization (ICH) Harmonized Tripartite Guidelines of Technical Requirements for Registration of Pharmaceuticals for Human Use, Organisation for Economic Co-operation and Development Guidelines for Testing of Chemicals(OECD), and/or Japan Ministry of Health, Labor, and Welfare (MHLW) Agency for Healthcare, Research and Quality Agency for Toxic Substances. Because this study was conducted in accordance with regulatory guidelines, alternatives could not be considered. Route of administration was based on intended delivery route for humans.

Summary:

This animal participated in b4 The purpose of this study was to evaluate the b4 b4 of a test article b4 to dogs for b4

b4 As with all of our protocols, the following statement was included, "Any animals showing signs of severe debility, toxicity, or if death appears imminent will be euthanized for humane reasons". This statement is included to allow intervention aimed to alleviate pain or distress.

The animal had completed the b4 and death occurred on b4 clinical observation, this dog snowed b4 and died before euthanasia could be administered.

ANNUAL REPORT OF RESEARCH FACILITY

Certificate Number: 51-R-0079

Customer Number: 21555

NOV 30 2005

Species: Beagle Dog

Study: 04136

Animal Number: [REDACTED] b4

Test Group/Sex: 4M

Justification:

Current FDA policy requires the use of rodent and non-rodent species for chemical compounds when data will be submitted for Individual New Drug application. Study designs follow the GLP for Non-clinical Laboratory Studies (FDA 21 CFR Part 58) and are based ICH Harmonized Tripartite Guidelines of Technical Requirements for Registration of Pharmaceuticals for Human Use, OECD, and/or MHLW Agency for Healthcare, Research and Quality Agency for Toxic Substances. Because this study was conducted in accordance with regulatory guidelines, alternatives could not be considered. Route of administration was based on intended delivery route for humans.

Summary:

This animal participated in [REDACTED] b4 The purpose of this study was to [REDACTED] (b)(4) [REDACTED] b4

[REDACTED] b4 . As with all of our protocols, the following statement was included, "Any animals showing signs of severe debility, toxicity, or if death appears imminent will be euthanized for humane reasons". This statement is included to allow intervention aimed to alleviate pain or distress.

The animal had completed the [REDACTED] (b)(4) and death occurred on [REDACTED] b4 observation on this dog showed [REDACTED] b4 The animal was found dead at the AM mortality check.

Species: Beagle Dogs

Study: 04542

Animal Number: [REDACTED] b4

Test Group/Sex: 3M

Justification:

This study was conducted under current Gene Logic Laboratories, Inc. (GLL) SOP's and in the spirit of GLP's. The compound provided by the sponsor was a novel compound with limited information regarding its effects.

Summary:

This animal participated in a study designed to determine [REDACTED] b4 [REDACTED] b4 the [REDACTED] b4 n

[REDACTED] b4 It was immediately decided to euthanize this dog [REDACTED] (b)(4) [REDACTED] (b)(4)

II. MONKEYS

Species: Monkey

Study: 03645

Animal Number: [REDACTED] b4

Test Group/Sex: N/A

Justification:

This animal was received as part of a shipment on 6/8/05 and was assigned to the stock colony.

Summary:

At the time of receipt, this animal was determined to have an [REDACTED] [REDACTED] were the only other noted observations. Despite intensive veterinary intervention, no observable improvement was noted. [REDACTED] (b)(4) the animal was found moribund. The technician immediately contacted appropriate personnel for approval to euthanize, but the animal died prior to intervention.

ANNUAL REPORT OF RESEARCH FACILITY

Certificate Number: 51-R-0079

Customer Number: 21555

NOV 30 2005

III. RABBITS

Species: Rabbit

Study: 04059

Animal Number: 10226

Test Group/Sex: 2M

Justification:

Current FDA policy requires the use of rodent and non-rodent species for chemical compounds when data will be submitted for Individual New Drug application. Study designs follow the GLP for Non-clinical Laboratory Studies (FDA 21 CFR Part 58) and are based on ICH Tripartite Guidelines, OECD, and/or MHLW. Because this study was conducted in accordance with regulatory guidelines, alternatives could not be considered. In this protocol [REDACTED] b4 [REDACTED] which the test article was intended to treat.

Summary:

This animal participated in a study involving the [REDACTED] (b)(4) [REDACTED] of rabbits [REDACTED] b4 [REDACTED] the animals were dosed with a compound intended to potentially reverse this condition. The animal had the [REDACTED] (b)(4) [REDACTED] performed on [REDACTED] (b)(4) [REDACTED]. The dosing was administered [REDACTED] (b)(4) [REDACTED]. The animal had no observations on the day of [REDACTED] b4 [REDACTED] or on [REDACTED] (b)(4) [REDACTED] when the animal was found dead. [REDACTED] b4 [REDACTED] b4 [REDACTED]

IV. GUINEA PIGS

Species: Guinea Pig

Study: 04062

Animal Number: 10640

Test Group/Sex: 7F

Justification:

This study was conducted under current GLL SOP's and in the spirit of GLP's. This study was conducted under an Inter-Institutional agreement, and was performed by technicians from both facilities.

Summary:

This animal was involved in [REDACTED] b4 [REDACTED] study. The animal was [REDACTED] b4 [REDACTED]. On [REDACTED] b4 [REDACTED] the animal was found dead. The animal did not show any signs of toxicity prior to finding it deceased. It cannot be determined what caused the sudden death of this animal, although it may have been test article related. It is GLL's intention to alleviate any pain or suffering whenever possible; however there were no previous indications of toxicity or distress associated with this animal.

Species: Guinea Pig

Study: 04062

Animal Number: 10662

Test Group/Sex: 11F

Justification:

This study was conducted under current GLL SOP's and in the spirit of GLP's. This study was conducted under an Inter-Institutional agreement, and was performed by technicians from both facilities.

Summary:

This animal was involved [REDACTED] b4 [REDACTED] study. The animal was [REDACTED] b4 [REDACTED]. On [REDACTED] b4 [REDACTED] the animal was found dead. The animal did not show any signs of toxicity prior to finding it deceased. It cannot be determined what caused the sudden death of this animal, although it may have been test article related. It is GLL's intention to alleviate any pain or suffering whenever possible; however there were no previous indications of toxicity or distress associated with this animal.

ANNUAL REPORT OF RESEARCH FACILITY

Certificate Number: 51-R-0079

Customer Number: 21555

NOV 30 2005

Species: Guinea Pig

Study: 04065

Animal Number: 10709

Test Group/Sex: 7F

Justification:

This study was conducted under current GLL SOP's and in the spirit of GLP's. This study was conducted under an Inter-Institutional agreement, and was performed by technicians from both facilities.

Summary:

This animal was involved in a [b4] study. The animal was [b4] On [b4] the appropriate personnel were contacted, however the animal died before any relief could be provided.

Species: Guinea Pig

Study: 04221.002

Animal Number: 11083

Test Group/Sex: 11F

Justification:

This study was conducted under current GLL SOP's and in the spirit of GLP's. This study was conducted under an Inter-Institutional agreement, and was performed by technicians from both facilities.

Summary:

This animal was involved in [b4] study. The animal was [b4] On [b4] the animal was found dead. The animal did not show any other signs of toxicity prior to finding the animal deceased. It cannot be determined what caused the sudden death of this animal, although it may have been [b4] related. It is GLL's intention to alleviate any pain or suffering whenever possible; however there were no previous indications of toxicity or distress associated with this animal.

Species: Guinea Pig

Study: 04221.002

Animal Number: 11073

Test Group/Sex: 9F

Justification:

This study was conducted under current GLL SOP's and in the spirit of GLP's. This study was conducted under an Inter-Institutional agreement, and was performed by technicians from both facilities.

Summary:

This animal was involved [b4] study. The animal was [b4] On [b4] the animal was found dead. [b4] and [b4] The appropriate personnel were contacted, however the animal died before euthanasia could be carried out.

Species: Guinea Pig

Study: 04221.004

Animal Number: 11187

Test Group/Sex: 7F

Justification:

This study was conducted under current GLL SOP's and in the spirit of GLP's. This study was conducted under an Inter-Institutional agreement, and was performed by technicians from both facilities.

Summary:

This animal was involved in a [b4] study. The animal was [b4] the animal was found dead. The animal did not show any signs of toxicity prior to being found deceased. It cannot be determined what caused the sudden death of this animal, although it may have been [b4] related. It is GLL's intention to alleviate any pain or suffering whenever possible; however there were no previous indications of toxicity or distress associated with this animal.

ANNUAL REPORT OF RESEARCH FACILITY

Certificate Number: 51-R-0079

Customer Number: 21555

NOV 30 2005

Species: Guinea Pig

Study: 04221.007

Animal Number: 11308

Test Group/Sex: 1F

Justification:

This study was conducted under current GLL SOP's and in the spirit of GLP's. This study was conducted under an Inter-Institutional agreement, and was performed by technicians from both facilities.

Summary:

This animal was involved in a [b4] study. [b4] the animal was found dead. The animal did not show any signs of toxicity prior to being found deceased. It cannot be determined what caused the sudden death of this animal, although it may have been (b)(4) related. It is GLL's intention to alleviate any pain or suffering whenever possible; however there were no previous indications of toxicity or distress associated with this animal.

Species: Guinea Pig

Study: 04221.009

Animal Number: 11457

Test Group/Sex: 4F

Justification:

This study was conducted under current GLL SOP's and in the spirit of GLP's. This study was conducted under an Inter-Institutional agreement, and was performed by technicians from both facilities.

Summary:

This animal was involved in a [b4] study [b4] the animal was found dead. The animal did not show any signs of toxicity prior to finding the animal deceased. It cannot be determined what caused the sudden death of this animal, although it may have been (b)(4) related. It is GLL's intention to alleviate any pain or suffering whenever possible; however there were no previous indications of toxicity or distress associated with this animal.

Species: Guinea Pig

Study: 04221.012

Animal Number: 11586

Test Group/Sex: 8 F

Justification:

This study was conducted under current GLL SOP's and in the spirit of GLP's. This study was conducted under an Inter-Institutional agreement, and was performed by technicians from both facilities.

Summary:

This animal was involved [b4] study. The animal [b4] In spite of Veterinary intervention, the health of the animal continued to deteriorate. The animal was found dead on [b4]

Species: Guinea Pig

Study: 04221.017

Animal Number: 11817

Test Group/Sex: 12F

Justification:

This study was conducted under current GLL SOP's and in the spirit of GLP's. This study was conducted under an Inter-Institutional agreement, and was performed by technicians from both facilities.

Summary:

This animal was involved in a [b4] study. The animal was (b)(4) the animal was found dead. The animal did not show any signs of toxicity prior to finding the animal deceased. It cannot be determined what caused the sudden death of this animal, although it may have been (b)(4) related. It is GLL's intention to alleviate any pain or suffering whenever possible; however there were no previous indications of toxicity or distress associated with this animal.

ANNUAL REPORT OF RESEARCH FACILITY

Certificate Number: 51-R-0079

Customer Number: 21555

NOV 8 2005

Species: Guinea Pig

Study: 04221.025

Animal Number: 12983

Test Group/Sex: 7F

Justification:

This study was conducted under current GLL SOP's and in the spirit of GLP's. This study was conducted under an Inter-Institutional agreement, and was performed by technicians from both facilities.

Summary:

This animal was involved in a [b4] study. [b4]
the animal was found dead. It cannot be determined what caused the sudden death of this animal, although it may have been [b4] related. It is GLL's intention to alleviate any pain or suffering whenever possible; however there were no other observations associated with this animal after [b4]

Species: Guinea Pig

Study: 04221.035

Animal Number: 12596

Test Group/Sex: 7F

Justification:

This study was conducted under current GLL SOP's and in the spirit of GLP's. This study was conducted under an Inter-Institutional agreement, and was performed by technicians from both facilities.

Summary:

This animal [b4] After [b4]
[b4] was found dead. The animal did not show any signs of illness prior to finding the animal deceased. It cannot be determined what caused the sudden death of this animal, although it may have been [b4] It is GLL's intention to alleviate any pain or suffering whenever possible; however there were no previous indications of illness or distress associated with this animal.

Species: Guinea Pig

Study: 04221.041B

Animal Number: 13495

Test Group/Sex: 12F

Justification:

This study was conducted under current GLL SOP's and in the spirit of GLP's. This study was conducted under an Inter-Institutional agreement, and was performed by technicians from both facilities.

Summary:

This animal was involved in [b4] study. The animal [b4]
the animal was found dead. The animal did not show any signs of toxicity prior to finding the animal deceased. It cannot be determined what caused the sudden death of this animal, although it may have been [b4] related. It is GLL's intention to alleviate any pain or suffering whenever possible; however there were no previous indications of toxicity or distress associated with this animal.